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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,424	05/23/2001	Victor M. Markowitz	4010US (43413-221712)	8455

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/862,424	Applicant(s) MARKOWITZ, VICTOR M.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.
2. Claims 1-14 are examined on the merits.

Claim Objections

3. The disclosure is objected to because of the following informalities: Specific to Claim 3, line 3, the word "if" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
1. Claim 1 is regarded as indefinite because the Applicant fails to support the method of the preamble with active steps. The active steps of the claim comprise of defining new classes and associations, grouping genes and annotating genes. However, the active steps of each claim do not help the Applicant accomplish the intended goal of the method, integrating multiple gene databases, in the preamble of the said claims. Nor do the active steps clearly and definitively establish support for the method, integrating multiple gene databases, within the preamble. A question that comes to mind is which component, the preamble or the active steps, of the claims is controlling these claims. Currently, it is inconclusive as to which component is controlling the

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claims or how one is to integrate multiple gene databases according to these methods. Claims 2-7 are rejected due to being directly or indirectly dependent from claim 1.

6. Specific to claim 2, line 3, and claim 9, line 4, the phrase “known and not known” causes the claim to be vague and indefinite. It is unclear what criteria are being used to determine whether groups are known or not known (sequence availability, functional characterization or confirmed gene). It is unclear what is meant by grouping unknown data, due to thus not knowing what to group. Clarification of the metes and bounds is required. Claims 5-7 and 12-14 are rejected due to being directly or indirectly dependent from claims 2 and 9, respectively.

7. Specific to claim 3, line 3, and claim 10, line 4, the phrase “automatic annotation” causes the claim to be vague and indefinite. It is unclear what criteria are being used to determine that gene fragment annotation is automatic (assigning annotation data, updating annotation data or editing sequence data). Is automatic a software function or a predetermined action? Clarification of the metes and bounds is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eckman et al. (1998).

10. The above publication by Eckman et al. discloses a method and system, the Merck Gene Index (MGI) browser, for integrating gene databases and gene finding, gene characterization and

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EST data mining. "The MGI browser integrates data from a variety of sources and storage formats, both local and remote, using an eclectic integration strategy, including a federation of relational databases, a local data warehouse and simple hypertext links. Data currently integrated include: LENS cDNA clone and EST data, dbEST protein and non-EST nucleic acid similarity data, WashU sequence chromatograms. Entrez sequence and Medline entries, and UniGene gene clusters" (Abstract). "The ultimate goal of the Merck-sponsored EST project is to produce a gene index to the human genome (MGI), a non-redundant set of clones and sequences each representing a distinct gene. Such an index can be a critical resource in studies of gene finding, gene characterization and gene expression...When a 3' EST is assigned to an index class, all ESTs on its clone, both 5' and 3', are also assigned to the class...The MGI data set is coordinated with the associated cDNA clones, as individual clones, set of clones (Page 2, column 2, lines 27-32 through Page 3, column 1, lines 4-15). Each new 3' EST is compared in turn against the index. If the EST is equivalent to an index entry, then the underlying cDNA clones of the new EST and the index entry EST are assumed to be derived from the same genes. The EST is then placed into the index class represented by that entry. If the EST is not equivalent to any existing entry, we assume that the gene represented by the underlying cDNA clone is not represented by any cDNA clone already in the index. A new index class is then created with the EST as its representative sequence (Page 6, columns 1 and 2 through page 7, column 1, lines 1-14). "There are at present three main ways to search the integrated databases that the browser accesses: by EST accession number, text search of EST definition lines, and index class id" (Page 7, column 1, lines 16-19, also Figure 3). The MGI browser has been used for identifying ESTs that are potentially novel members of gene families of interest; choosing broadly

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representative set of cDNA clones for use in differential expression studies; and identifying candidate disease genes (Page 10, column 2, lines 9-12). "New w will be developed to validate existing index classes with 3' ESTs that fail the screening process, and to assign putative index classes for non-directionally cloned cDNA and directionally cloned cDNAs that have not been successfully sequenced on the 3' end" (Page 10, column 2, line 20 through page 11, column 1, lines 1-6). The system of MGI is 4X200 MHZ processor Silicon Graphics Challenge. This machine functions as a database, WWW, file, and compute server (Page 3, column 2, lines 31-34; also Figure 11).

11. Further, Eckman et al. discloses that MGI contains IMAGE clone data and dbEST sequence similarity data (Page 3, column 2, lines 12-14). It is well known in the art that sequence similarity data is derived from sequence-based matching. Further, Lenon et al. is provided not as prior art but only as a reference to disclose the data related to IMAGE clone contained in MGI is manually annotated and curated (See entire document).

12. Clearly, Eckman et al. (1998) anticipates every limitation of claims 1-14.

CONCLUSION

13. NO CLAIM IS ALLOWED.

14. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

17. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/24/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER